

110TH CONGRESS  
1ST SESSION

# H. R. 3061

To amend title XVIII of the Social Security Act to require that Medicare prescription drug plans using formularies cover all drugs included in 6 specified therapeutic categories, to establish protective requirements for coverage determinations, reconsiderations, and appeals related to such drugs, and to require annual reports on such determinations, reconsiderations, and appeals.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 17, 2007

Mr. DOGGETT (for himself, Mr. ABERCROMBIE, Mr. ALLEN, Mr. DAVIS of Illinois, Mr. EMANUEL, Mr. ENGEL, Mr. AL GREEN of Texas, Mr. HINCHHEY, Ms. KAPTUR, Mr. LARSON of Connecticut, Ms. MCCOLLUM of Minnesota, Mr. McDERMOTT, and Mr. STARK) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XVIII of the Social Security Act to require that Medicare prescription drug plans using formularies cover all drugs included in 6 specified therapeutic categories, to establish protective requirements for coverage determinations, reconsiderations, and appeals related to such drugs, and to require annual reports on such determinations, reconsiderations, and appeals.

1 *Be it enacted by the Senate and House of Representa-*  
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Part D Drug  
 5 Class Protection Act of 2007”.

6 **SEC. 2. SPECIAL TREATMENT UNDER MEDICARE PART D**  
 7 **FOR DRUGS IN 6 SPECIFIED THERAPEUTIC**  
 8 **CATEGORIES.**

9 (a) MEDICARE PART D FORMULARIES REQUIRED TO  
 10 COVER ALL DRUGS IN 6 SPECIFIED THERAPEUTIC CAT-  
 11 EGORIES.—

12 (1) IN GENERAL.—Section 1860D–4(b)(3) of  
 13 the Social Security Act (42 U.S.C. 1395w–  
 14 104(b)(3)) is amended—

15 (A) in subparagraph (C)(i), by inserting “,  
 16 except as provided in subparagraph (G),” after  
 17 “although”; and

18 (B) by inserting after subparagraph (F)  
 19 the following new subparagraph:

20 “(G) REQUIRED INCLUSION OF DRUGS IN  
 21 CERTAIN THERAPEUTIC CATEGORIES AND  
 22 CLASSES.—

23 “(i) REQUIREMENT.—The formulary  
 24 must include, subject to clause (iii), all or  
 25 substantially all drugs in each of the fol-

lowing therapeutic categories of covered  
part D drugs:

“(I) Immunosuppressants.

“(II) Antidepressants.

“(III) Antipsychotics.

“(IV) Anticonvulsants.

“(V) Antiretrovirals.

“(VI) Antineoplastics.

“(ii) COVERAGE OF ALL UNIQUE DOS-  
AGE FORMS.—To meet the requirement  
under clause (i), the formulary must in-  
clude all covered part D drugs and unique  
dosages and forms of such drugs in the  
categories specified in such clause, except  
for—

“(I) multi-source brands of the  
identical molecular structure;

“(II) extended release products  
in the case that the immediate release  
product involved is included on the  
formulary;

“(III) products that have the  
same active ingredient; and

1 “(IV) dosage forms that do not  
2 provide a unique route of administra-  
3 tion, such as tablets and capsules.

4 “(iii) APPLICATION TO NEW FDA-AP-  
5 PROVED DRUGS.—In the case of a drug  
6 that becomes a covered part D drug and  
7 that is included in a category specified in  
8 clause (i), clause (i) shall apply to such  
9 drug 30 days after the drug has been  
10 placed on the market. Nothing in the pre-  
11 vious sentence shall be construed as pre-  
12 venting a pharmacy and therapeutic com-  
13 mittee from advising a PDP sponsor of a  
14 prescription drug plan on the clinical ap-  
15 propriateness of formulary management  
16 practices and policies related to new drugs  
17 in such categories.

18 “(iv) UTILIZATION MANAGEMENT  
19 TOOLS NOT PERMITTED.—A PDP sponsor  
20 of a prescription drug plan may not apply  
21 a utilization management tool, such as  
22 prior authorization or step therapy, to a  
23 drug required under clause (i) to be in-  
24 cluded on the formulary.

25 “(v) RULES OF CONSTRUCTION.—

1 “(I) ISSUANCE OF GUIDANCE OR  
2 REGULATIONS TO ESTABLISH FOR-  
3 MULARY OR UTILIZATION MANAGE-  
4 MENT REQUIREMENTS PERMITTED.—  
5 Nothing in this subparagraph shall be  
6 construed as prohibiting the Secretary  
7 from issuing guidance or regulations  
8 to establish formulary or utilization  
9 management requirements under this  
10 section for any category or class of  
11 covered part D drugs if such guidance  
12 or regulations are consistent with the  
13 requirements of this subparagraph.

14 “(II) ADDITIONAL THERAPEUTIC  
15 CATEGORIES PERMITTED.—Nothing in  
16 this subparagraph shall be construed  
17 as prohibiting the Secretary from in-  
18 cluding any additional therapeutic cat-  
19 egory or class of covered part D drugs  
20 under clause (i) for purposes of this  
21 subparagraph.”.

22 (2) EFFECTIVE DATE.—The amendments made  
23 by paragraph (1) shall apply to plan years beginning  
24 on or after January 1, 2008.

1 (b) SPECIAL REQUIREMENTS FOR COVERAGE DE-  
2 TERMINATIONS, RECONSIDERATIONS, AND APPEALS FOR  
3 DRUGS INCLUDED IN SPECIFIED THERAPEUTIC CAT-  
4 EGORIES.—

5 (1) IN GENERAL.—Section 1860D–4(g) of the  
6 Social Security Act (42 U.S.C. 1395w–104(g)) is  
7 amended by adding at the end the following new  
8 paragraph:

9 “(3) RECONSIDERATION OF DETERMINATIONS  
10 RELATED TO DRUGS INCLUDED IN SPECIFIED  
11 THERAPEUTIC CATEGORIES CONDUCTED BY INDE-  
12 PENDENT REVIEW ENTITY.—With respect to a part  
13 D eligible individual enrolled in a prescription drug  
14 plan, in the case of a determination under this sub-  
15 section that denies such individual coverage (in  
16 whole or in part) of a drug in a category specified  
17 in subsection (b)(3)(G)(i), the individual may re-  
18 quest that the reconsideration of such determination  
19 authorized under section 1852(g)(2) (as applied by  
20 paragraph (1)) be conducted by the independent,  
21 outside entity described in paragraph (4) of section  
22 1852(g) in accordance with the procedures for an  
23 expedited reconsideration under paragraph (3) of  
24 such section.

1           “(4) REQUIRED COVERAGE OF DRUGS IN-  
2           CLUDED IN SPECIFIED THERAPEUTIC CATEGORIES  
3           DURING DETERMINATIONS, RECONSIDERATIONS,  
4           AND APPEALS.—If a part D eligible individual en-  
5           rolled in a prescription drug plan offered by a PDP  
6           sponsor requests a redetermination or reconsider-  
7           ation under this subsection (or an appeal under sub-  
8           section (h)) with respect to an utilization manage-  
9           ment requirement or denial of coverage (in whole or  
10          in part) of a drug in a category specified in sub-  
11          section (b)(3)(G)(i), such sponsor shall provide such  
12          individual with coverage of such drug as prescribed  
13          during the pendency of such redetermination, recon-  
14          sideration, or appeal until 60 days after the date of  
15          receipt of a written notification of—

16                 “(A) in the case that the individual does  
17                 not request a reconsideration or appeal, the de-  
18                 termination on such redetermination;

19                 “(B) in the case that the individual re-  
20                 quests a reconsideration but not an appeal, the  
21                 determination on such reconsideration; or

22                 “(C) in the case that the individual re-  
23                 quests an appeal, the determination on such ap-  
24                 peal or the dismissal of the appeal;

except that in no case shall such coverage end before the end of the period in which an individual may file an appeal with respect to the determination involved.”.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to requests for redeterminations, reconsiderations, and appeal hearings made on or after the effective date described in subsection (a)(2).

(c) REPORTING REQUIREMENTS FOR DRUGS INCLUDED IN SPECIFIED THERAPEUTIC CATEGORIES.—

(1) IN GENERAL.—Section 1860D–4(b) of the Social Security Act (42 U.S.C. 1395w–104(b)) is amended by adding at the end the following new paragraph:

“(4) REPORTING REQUIREMENTS FOR DRUGS INCLUDED IN SPECIFIED THERAPEUTIC CATEGORIES.—

“(A) REPORTS BY PDP SPONSORS.—A PDP sponsor offering a prescription drug plan shall submit to the Secretary (in a form and manner specified by the Secretary), with respect to drugs in a category of covered part D drugs specified in subsection (b)(3)(G)(i), information on the number of favorable and unfavorable de-



1 cisions under the plan relating to coverage de-  
2 terminations, redeterminations, reconsider-  
3 ations, appeals, and enrollee requests for excep-  
4 tions to formulary policies for such drugs.

5 “(B) REPORT TO CONGRESS.—The Sec-  
6 retary shall submit an annual report to Con-  
7 gress summarizing the information submitted  
8 under subparagraph (A) and shall publish each  
9 report in the Federal Register.”.

10 (2) EFFECTIVE DATE.—The amendment made  
11 by paragraph (1) shall apply to prescription drug  
12 plans and MA plans for plan years beginning on or  
13 after the effective date described in subsection  
14 (a)(2).

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